AMENDED IN ASSEMBLY MARCH 27, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2408

Introduced by Assembly Member ~~Calderon~~ *Negrete McLeod*

February 23, 2006

~~An act to amend Section 10153.4 of, to amend, repeal, and add Sections 10156.6, 10156.7, and 10215 of, to add and repeal Section 10153.10 of, and to repeal Section 10154 of, the Business and Professions Code, relating to real estate salespersons.~~ *An act to amend Sections 4036, 4037, 4050, 4051, 4052, 4112, 4120, 4201, 4207, 4301, and 4306.5 of, to amend, renumber, and add Section 4052.1 of, to add Sections 4052.2 and 4052.3 to, and to repeal and add Section 4302 of, the Business and Professions Code, relating to pharmacies.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2408, as amended, ~~Calderon~~ *Negrete McLeod*. ~~Real estate salespersons: conditional licensure.~~ *Pharmacies.*

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacies by the Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime.

Existing law defines a pharmacist and a pharmacy, requires pharmacists and pharmacies to be licensed by the board, and authorizes a licensee to engage in certain activities. Existing law also sets forth activities that constitute unprofessional conduct for a pharmacist to engage in.

This bill would require a pharmacist to be a natural person, and would entitle a licensed pharmacist to practice pharmacy within or outside of a licensed pharmacy. The bill would revise the activities in

which a pharmacist may engage, including the adjustment of prescriptions and provisions of cognitive services, would revise the pharmacist's responsibilities and requirements with regard to certain activities, and would make certain additional acts or omissions unprofessional conduct. The bill would revise the definition of a pharmacy to include, among other things, all pharmacies in which the profession of pharmacy is practiced. The bill would list different types of pharmacies and would require a pharmacy or nonresident pharmacy to specify its type in its application for licensure and to update the board if that information changes. The bill would make it unlawful for an unlicensed person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other health care providers.

Existing law defines a nonresident pharmacy and requires a nonresident pharmacy to meet certain criteria, including registration with the board. Existing law prohibits an unregistered nonresident pharmacy from engaging in certain activities, including selling or distributing dangerous drugs or dangerous devices in this state through any person or media other than a licensed wholesaler. Existing law requires a nonresident pharmacy to disclose to the board the location, names, and titles of specified persons, including all pharmacists dispensing controlled substances, dangerous drugs, or dangerous devices to residents of California. Existing law authorizes the board to deny, revoke, or suspend a nonresident registration for failure to comply with specified requirements or for conduct that causes serious bodily or psychological injury to a California resident, in specified circumstances.

This bill would revise the definition of a nonresident pharmacy to require shipping, mailing, or delivering directly to patients in California, and to include a pharmacy located outside of the state that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. The bill would delete the requirement that a nonresident pharmacy must disclose the location, names, and titles of pharmacists, and the prohibition against a nonresident pharmacy selling or distributing dangerous drugs or devices in California through any person or media other than a licensed wholesaler. This bill would also delete the authorization for the board to deny, revoke, or suspend a nonresident registration for

failure to comply with specified requirements or for conduct causing serious bodily harm or psychological injury to a California resident, and would instead authorize the board to deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment, or take any other action against a nonresident pharmacy that it may take against a resident pharmacy. The bill would also authorize the board to report violations of laws or regulations by a nonresident pharmacy to its regulatory or licensing agency.

This bill would revise and recast related provisions of the Pharmacy Law.

Because this bill would create new requirements and prohibitions under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~Existing law, the Real Estate Law, provides for the licensure and regulation of real estate salespersons by the Department of Real Estate. Under that law, an applicant for licensure as a real estate salesperson is required to submit to the Real Estate Commissioner evidence of the successful completion of specified courses in real estate either prior to issuance of the license or within 18 months after its issuance.~~

~~This bill would, for persons who apply for licensure on or after January 1, 2007, delete the provisions from the Real Estate Law that allow an applicant to submit evidence of his or her completion of the real estate courses within 18 months after issuance of the license.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. Section 4036 of the Business and Professions Code is amended to read:

4036. "Pharmacist" means a *natural* person to whom a license has been issued by the board, under Section 4200, except

as specifically provided otherwise in this chapter. *The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.*

SEC. 2. Section 4037 of the Business and Professions Code is amended to read:

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. *Only a "dispensing pharmacy," as defined in subdivision (b), may possess, prepare, manufacture, derive, compound, repackage, furnish, sell, or dispense controlled substances, dangerous drugs, or dangerous devices. In all other respects, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to all of the types of pharmacies listed in subdivision (b).* ~~"Pharmacy"~~

(b) "Pharmacy" includes, but is not limited to, ~~any~~ *all of the following:*

(1) A "dispensing pharmacy," which is any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

~~(b)~~

(2) A "prescription processing pharmacy," which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board engage in or supervise drug order or prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient or prescriber contact, patient profile review, and allergy and drug-interaction review.

(3) An "advice/clinical center pharmacy," which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.

(c) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(d) "Pharmacy" shall not include a clinic licensed under Section 4180 or Section 4190.

SEC. 3. Section 4050 of the Business and Professions Code is amended to read:

4050. (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. *Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.*

SEC. 4. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) *The holder of an unexpired and active pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:*

(1) Interpreting, verifying, and implementing drug orders and prescriptions.

(2) Dispensing pursuant to legitimate drug orders and prescriptions.

(3) Ensuring proper drug storage, documentation, inventory, labeling, and record-keeping.

(4) Maintaining accurate, complete, and confidential patient profiles and records.

(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy.

(6) Designing and implementing quality assurance procedures and protocols.

(7) Compounding drug products pursuant to prescription and for prescriber office use.

(8) Maintaining safe, secure, and sanitary conditions in licensed premises.

(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation.

(10) Collaborating with prescribers and other health care providers regarding patient care.

(11) Implementing standardized procedures and protocols regarding patient care.

(12) Administering or furnishing drugs or biologicals, where permitted by law.

(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law.

(14) Any other pharmacy functions authorized by this chapter.

(b) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist *licensed* under this chapter.

~~(b)~~

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(d) Notwithstanding any other law, a pharmacist *licensed under this chapter* may authorize the initiation *or adjustment* of a prescription, pursuant to Section 4052, and otherwise provide *cognitive services,* clinical advice or information, or patient consultation if all of the following conditions are met:

(1) The *cognitive service,* clinical advice, or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription *records*, patient ~~profile~~ *profiles*, or other relevant medical information for purposes of *cognitive services,* patient and clinical consultation,

and advice, *and appropriately reviews that information before performing any of these functions*.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) The pharmacist authorizing initiation or adjustment of a prescription, or cognitive services such as clinical advice, information, or patient consultation, sets forth a complete log and description of all patient records and other patient-specific information, including any test results or other pertinent data, used, consulted, or relied on by the pharmacist during the performance of the function. The board may by regulation further define the required content of the log and description. This log and description shall be maintained in a readily retrievable form, and provided to the board upon request, for a period of at least three years from the date of performance of the function. The underlying patient records and other patient-specific information used, consulted, or relied on by the pharmacist during the performance of the function may be maintained elsewhere and not kept with the log and description, as long as those records and that information are readily retrievable and provided to the board upon request for a period of at least three years from the date of performance of the function. Otherwise, a duplicate copy of the patient records and patient-specific information used, consulted or relied on shall become part of the records maintained. Where the function to which the log and description pertains is performed on the premises of a licensed pharmacy, the obligation to keep and maintain the foregoing records extends to the pharmacy and its pharmacist-in-charge, and to the pharmacist performing the function. Where the function to which the log and description pertains is performed outside of the premises of a licensed pharmacy, the obligation to keep and maintain the foregoing records extends only to the performing pharmacist.

SEC. 5. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication~~ *drug product* to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform ~~the following~~ procedures or functions in a licensed health care facility ~~in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~ *as authorized by Section 4052.1*.

(5) ~~(A)~~ Perform ~~the following~~ procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician,~~in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):~~

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the~~

~~individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

~~(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~ *as authorized by Section 4052.2.*

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide *cognitive services such as drug utilization review, medication therapy management,* consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) ~~(A)~~ Furnish emergency contraception drug therapy ~~in accordance with either of the following:~~ *as authorized by Section 4052.3.*

~~(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer~~

~~with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~

~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

~~(c)~~

(9) Administer immunizations pursuant to a protocol with a prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

~~(d)~~

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

~~(e)~~

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 6. Section 4052.1 of the Business and Professions Code is amended and renumbered to read:

~~4052.1.~~

4052.4. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

SEC. 7. Section 4052.1 is added to the Business and Professions Code, to read:

4052.1. (a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals,

including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

SEC. 8. Section 4052.2 is added to the Business and Professions Code, to read:

4052.2. (a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or

physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

SEC. 9. Section 4052.3 is added to the Business and Professions Code, to read:

4052.3. (a) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered

and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

SEC. 10. Section 4112 of the Business and Professions Code is amended to read:

4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices ~~into~~ *directly to patients in* this state*, or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state,* shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process

in this state, (2) all principal corporate officers, if any, *and* (3) all general partners, if any~~, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state~~. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, *or* partner~~, or pharmacist~~.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require

face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(h) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(j) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

SEC. 11. Section 4120 of the Business and Professions Code is amended to read:

4120. (a) ~~A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.~~

~~(b)~~ Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(b) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037. The applicant shall immediately notify the board of any requested addition, deletion, or other change in specified pharmacy type prior to licensure. After licensure, any change in specified pharmacy type shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to implementation or elimination of any activities permitted by the added, deleted, or changed type designation.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

SEC. 12. Section 4201 of the Business and Professions Code is amended to read:

4201. (a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) *Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037. The applicant shall immediately notify the board of any requested addition, deletion, or other change in specified pharmacy type prior to licensure. After licensure, any change in specified pharmacy type shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to implementation or elimination of any activities permitted by the added, deleted, or changed type designation.*

(c) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

~~(c)~~

(d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or

stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

~~(d)~~

(e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

~~(e)~~

(f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

~~(f)~~

(g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

~~(g)~~

(h) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

~~(h)~~

(i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

~~(i)~~

(j) For licenses referred to in subdivisions (f), (g), and (h), any change in the proposed beneficial ownership interest shall be

reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

SEC. 13. Section 4207 of the Business and Professions Code is amended to read:

4207. (a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices*, or to the performance or provision of prescription or drug order processing or review services or cognitive services,* that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative ~~Procedures~~ *Procedure* Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

SEC. 14. Section 4301 of the Business and Professions Code, as added by Section 44 of Chapter 857 of the Statutes of 2004, is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

(j) The violation of any of the statutes of this state, *of any other state*, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13

(commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board *or by any other state or federal regulatory agency*.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.

(t) This section shall become operative on January 1, 2006.

SEC. 15. Section 4303 of the Business and Professions Code is repealed.

~~4303. (a) The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4112, 4124, or 4340, for any significant or repeated failure to comply with Section 4074 or 4076, or for failure to comply with Section 11164 of the Health and Safety Code.~~

~~(b) The board may deny, revoke, or suspend a nonresident pharmacy registration for conduct that causes serious bodily or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or~~

~~licensing agency fails to initiate an investigation within 45 days of the referral.~~

SEC. 16. Section 4303 is added to the Business and Professions Code, to read:

4303. (a) The board may report any violation of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to the appropriate regulatory or licensing agency of the state in which a nonresident pharmacy is a resident.

(b) The board may deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon such action might be taken against a resident pharmacy.

SEC. 17. Section 4306.5 of the Business and Professions Code is amended to read:

4306.5. *(a)* Unprofessional conduct for a pharmacist may include ~~acts~~ *any of the following:*

(1) Acts or omissions that involve, in whole or in part, the *inappropriate* exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(2) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices or with regard to the provision of cognitive services.

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

SEC. 18. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

All matter omitted in this version of the bill appears in the bill as introduced in Assembly, February 23, 2006 (JR11)

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